OCT 0 8 2002

K020507

OLYMPUS

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Olympus Neuroendoscopes

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDS 1990 and 21 CFR Part 807.92

A. Submitter's Name, Address, Phone, Contact Person and Summary Date

Manufacturer of subject device:	Olympus Winter & Ibe Keuhnstr. 61 D-22045 Hamburg Germany
Registration number:	8010313
Contact Person:	Laura Storms-Tyler Olympus America Inc. Two Corporate Center Drive Melville NY 11747-3157 Telephone: (631) 844-5688

B. Device Name

Device Name: Olympus Neuroendoscopes

Common/Usual Name: Neurological endoscopes

Classification Name: Neurological endoscope

Classification: 21 CFR 882.1480
Class II

C. Predicate Devices:

Olympus Neuroendoscopes (K971340)

D. Device Description

The Olympus Neuroendoscope is a rigid endoscope indicated for intraventricular (and other intracranial CSF-containing cavities), subarachnoid and brain parenchymal environments.

E. Intended Use of Device

The Olympus Neuroendoscopes are intended for viewing the ventricles of the brain and for use in endoscopic assisted microsurgery for cerebral aneurysms and shunt placement and for visualization of tumors, cysts and neurovascular compression syndromes.

F. Comparison to Predicate Devices

Item	Predicate device, model A7594A	Subject device, S-1349/1	Subject device, S-1349/2	Subject device, S-1349/3	Subject device, S-1349/4
Telescope Diameter	Ø 4 mm	Ø 4 mm	Ø 2.7 mm	Ø 2.7 mm	Ø 2.7 mm
Telescope Total Length	218.5 mm	218.5 mm	225.3 mm	225.0 mm	233 mm
Telescope Working Length	158.1 mm	158.1 mm	158.1 mm	157.7 mm	156.7 mm
Lens Diameter	Ø 2.8 mm	Ø 2.8 mm	Ø 1.7 mm	Ø 1.7 mm	Ø 1.9 mm
Field of view	95.8°	95.8°	70.8°	68.4°	85°
Direction of view	0°	0°	0°	30°	70°
Best working distance	10 mm	10 mm	10 mm	10 mm	10 mm
Magnification	2.1	2.1	2.15	2.22	2.19

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2002

Ms. Laura Storms-Tyler
Director Regulatory Affairs and
Quality Assurance
Olympus America, Inc.
2 Corporate Center Drive
Melville, New York 11747

Re: K020507
Trade/Device Name: Olympus Neuroendoscope
Regulation Number: 882.1480
Regulation Name: Neurological endoscope
Regulatory Class: II
Product Code: GWG
Dated: July 3, 2002
Received: July 10, 2002

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020507

Device Name: Olympus Neuroendoscope

Indications for Use:

The Olympus Neuroendoscopes are intended for viewing the ventricles of the brain, for use in endoscopic assisted microsurgery for cerebral aneurysms, and shunt placement and for visualization of tumors, cysts and neurovascular compression syndromes.

(Please do not write below this line. Continue on another page is needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over-the-Counter Use

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020507